

GEORGE X. KAMBIC Ph.D.

PROFESSIONAL CAREER

- Philips Medical Systems 1986-1987, 1996 – current
- Philips acquired Marconi Medical Systems in October 2001, formerly Picker International
 - Director of Quality and Regulatory. June, 2000 – 9 reports
 - Maintain international regulatory compliance
 - Plan and implement a merger of worldwide quality systems
 - Manager of Engineering Process Assurance, 1999- May, 2000, 26 reports
 - Create and maintain Quality System records
 - Audit projects for FDA / MDD compliance
 - Create / update / teach Quality System procedures
 - Field testing of varied CT products
 - Support the field with physics and image quality measurements
 - Manager, CT Systems Test department
 - Verification and validation management of CT systems
 - Regulatory compliance with Design Controls
 - Design verification and validation procedures
 - 1996-1999, 11 reports
 - Installed inspection process in development engineering
 - Lectured and sold concept to developers and management
 - Brought in course instructor
 - Continued to teach internal course for inspections
 - Established standard test plans and procedures for alpha testing
 - Created Quality System procedures and electronic test records
 - Used historical test metrics to predict alpha test schedules
 - Enforced measurement of defect detection and validation for predictions
 - Enforced standard exit criteria for alpha test process
- Cleveland Clinic Foundation (CCF) 1995-1996
 - Manager of Quality Assurance in the Biomedical Engineering Department
 - Audited Artificial Heart Program to ISO and FDA standards
 - Led Animal Research Facility to regulatory compliance
- Rockwell International (RI) 1987-1995
 - Principal Engineer in Control Logic
 - Installed software inspection process
 - Audited programs to CMM and ISO standards
 - Responsible for systems testing of \$57M PLC program
 - Installed EVA project metrics for software teams
 - Created and headed a second systems testing department
- Johnson and Johnson (JNJ) 1975-1986
 - Technicare Medical Imaging Division
 - Wrote PMA's, IDE's and 510(k)'s
 - Took prototype systems into clinical practice
 - Created and headed a systems testing department
- Now leading a focused Quality and Regulatory Team responsible for worldwide compliance and Quality within the CT business line. Integrating three Quality Systems across three countries.

- Led a centralized Quality Assurance Department for CT, NM, and MR Strategic Business Unit groups. Developed focus on measurement and culture through Quality reporting, and TQM education. Focused on product quality as delivered to the customer. Led creation of Monthly Quality Report. Led revamping of customer complaint system. Led creation of cost of quality measurements in order to focus on costs to customers and Medical Systems.
- Directed system testing of systems including medical imaging techniques, and operational domain utility, including \$57M factory management system and ~1M\$ Computed Tomography Imaging systems. Developed and executed plans for product evaluation in the clinical environment. Led test teams in creating test plans, procedures and test summary reports. Test plans created from specifications developed through heavy interaction with the medical and process control communities.
- Developed a Quality System and Quality Manual in an academic research and development environment that had to meet FDA GMP and ISO 9000 requirements. Negotiated and led the medical academic community in the use of a configurable Quality System for compliance with ISO and / or FDA GMP / QSRs as needed..
- Software Process Improvement activities: led software metrics team to develop, install and use strong software project management techniques on new projects; sold project management on need for detailed effort expenditures for project predictions; created, taught and led software Inspection effort; CSQE and CQA certifications; have taught CSQE refresher course; helped to create, introduce and teach a business process improvement course
- NASA LEWIS RESEARCH CENTER, Cleveland, Ohio. 1972-1975

Postdoctoral Research Associate

EDUCATION

Ph.D., M.S., Plasma Physics - Rensselaer Polytechnic Institute, Troy, N.Y.
B.S. Physics, Minor in History - Carnegie Mellon University, Pittsburgh, PA

RELEVANT ACTIVITIES

IEEE, APS, ACM, ASQ, AAPM
Created and taught process improvement, CSQE and inspection courses
Publications on imaging, radiation dosimetry, software PI techniques